AGENDA

State and Public School Life and Health Insurance Board
Drug Utilization and Evaluation Committee

February 06, 2017

1:00 p.m.

EBD Board Room – 501 Building, Suite 500

I.	*Call to Order*	*Dr. Hank Simmons, Chairman*
II.	*Approval of Dec. 2, 2016 & Jan. 9, 2017 Minutes*	*Dr. Hank Simmons, Chairman*
III.	*Election of Officers*	*Dr. Hank Simmons, Chairman*
IV.	*DCWG Report*	*Dr. Geri Bemberg, UAMS*
V.	*Second Review*	*Dr. Geri Bemberg, Dr. Jill Johnson, UAMS*
VI.	*New Drugs*	*Dr. Jill Johnson, UAMS*
VII.	*Oral Antidiabetic Rebate Review*	*Dr. Rachael McCaleb, UAMS*
VIII.	*Opioid Discussion*	*Committee*
IX.	*EBD Report*	*Dr. Geri Bemberg*

2017 Upcoming Meetings

April 3, 2017, August 7, 2017, November 6, 2017

NOTE: All material for this meeting will be available by electronic means only asepse-board@dfa.arkansas.gov

Notice: Silence your cell phones. Keep your personal conversations to a minimum. Observe restrictions designating areas as "Members and Staff only"

State and Public School Life and Health Insurance Board
Drug Utilization and Evaluation Committee Minutes
February 6, 2017

The State and Public Life and Health Insurance Board, Drug Utilization and Evaluation Committee (DUEC) met on Monday, February 6, 2017 at 1:00 p.m., in the EBD Board Room, 501 Woodlane, Little Rock, AR.

Voting Members present:
Dr. Hank Simmons, Chairman
Dr. Kat Neill, Vice-Chairman
Dr. Scott Pace
Mike Boyd
Dr. William Golden
Dr. Appathurai Balamurugan
Laura Mayfield
Dr. John Kirtley

Non-Voting Members present:
Dr. Jill Johnson
Dr. Geri Bemberg

Members absent:

Chris Howlett, EBD Executive Director, Employee Benefits Division

OTHERS PRESENT
Jessica Akins, Rachael McCaleb, Nick Green, UAMS College of Pharmacy; Sherry Bryant, Ethel Whittaker, Rhoda Classen, Amanda Hood-Armstrong, Shay Burleson, Drew Higginbotham, Terri Freeman, Cecilia Walker, Eric Gallo, EBD; Marc Watts, ASEA; Amanda Camp, APA; Barry Felder, QualChoice; Linda Spencer, Active Health; Sandra Wilson, Active Health; Andy Davis, ADG; Sean Seago, Merck; Ronda Walthall, Arkansas Highway Department; Jon McGuire, GSK; Jim Chapman, ABBVIE; Suzanne Woodall, MedImpact; Stephen Carroll, Allcare Specialty; Frances Bauman, Nova Nordisk; Elizabeth Whittington, ACHI; BF, MedImpact; Erica Brumleve, GSK; Karyn Langley, QCA

CALL TO ORDER
Meeting was called to order by Dr. Hank Simmons, Chairman.

APPROVAL OF MINUTES
The request was made by Dr. Simmons to approve the December 2, 2016 & January 9, 2017 minutes. Dr. Pace made the motion to approve. Dr. John Kirtley seconded; all were in favor.

Minutes Approved.

Dr. Simmons outlined the statute for electing officers and recommended that the committee would elect officers at the April 4th meeting.

I. Delivery Coordination Workgroup Report: *by Dr. Geri Bemberg, UAMS*

Dr. Bemberg gave an update of medications reviewed by the DCWG Group. Topics covered included Chronic Lymphocytic Leukemia, Head and Neck Cancer, and Non-Small Cell Lung Cancer.

II. 2nd review of Drugs: *by Dr. Geri Bemberg, UAMS*

Dr. Bemberg reviewed Arestin, a subgingival minocycline, used for periodontitis. Several studies were reviewed, and it was recommended to exclude this medication from both pharmacy and medical due to the lack of comparative efficacy demonstrated in the clinical trials.
The committee recommended to exclude Arestin from pharmacy and medical coverage.

Dr. Golden reported the FDA is increasingly approving drugs with minimum to marginal to no clinical benefit demonstration. Therefore, the FDA approval is not a mandatory indication for coverage.

III. New Drugs: *by Dr. Jill Johnson, UAMS*

Dr. Jill Johnson reported on new drugs. The review covered products released September 5, 2016 – November 28, 2016.

A. Recommended Additions

1. Nonspecialty Medications

BRAND NAME	GENERIC NAME	PRICING (AWP)	INDICATION	SIMILAR THERAPIES ON FORMULARY	DUEC VOTE
Vaxchora	Cholera Vaccine	$270 (100ml)	Cholera prevention		Cover, Tier 3 PA

Dr. Pace motioned to cover at T3PA with CDC Guidelines as guidance to the staff. Dr. Kirtley seconded. All were in favor, motion approved.

2. Specialty Medications

BRAND NAME	GENERIC NAME	PRICING (AWP)	INDICATION	SIMILAR THERAPIES ON FORMULARY	DUEC VOTE
Stelara	Ustekinumab 130mg/26ml	$1,919.99/vial	Crohn disease, Plaque psoriasis, Psoriatic arthritis	Rebated category. Other Stelara strengths covered non-preferred Tier 4 PA	Cover, Tier 4 PA.
Inflectra	Infliximab-dyyb 100mg	$1,135.54/vial	Multiple Indications	Rebated category. Remicade on non-preferred	Cover, Tier 4 PA; use in place of Remicade.
Lartruvo	Olaratumab 500mg/50mL	$2,832/vial	Soft tissue sarcoma	Most covered antineoplastic agents are available T4PA	Cover, Tier 4 PA

BRAND NAME	GENERIC NAME	PRICING (AWP)	INDICATION	SIMILAR THERAPIES ON FORMULARY	DUEC VOTE
Vemlidy	Tenofovir alafenamide fumarate 25mg	$39.91/tab	Chronic Hep B		Cover, Tier 4 PA, QL #30/30d

Dr. Kirtley motioned to accept the specialty drugs recommendations with the exception of Exondys. Dr. Neill seconded; all were in favor.

B. Recommended Exclusions

1. Nonspecialty Medications

BRAND NAME	GENERIC NAME	PRICING (AWP)	INDICATION	SIMILAR THERAPIES ON FORMULARY	DUEC VOTE
Yosprala	Aspirin-omeprazole 81-40 mg, 325-40mg.	$6/tablet	Secondary prevention of CV and cerebrovascular events.	Aspirin & omeprazole covered tier 1 (MAC)	Exclude, code 13
GoNitro	Nitroglycerin powder pack 400mg	$8.17/pack	Treatment or prevention of angina pectoris	Nitroglycerin caps & sublingual tabs available tier 1 (MAC)	Exclude, code 13
Ameluz	Aminolevulinic acid 10%	$324	Actinic Keratoses		Exclude through pharmacy. Cover through medical.
Bromsite	Bromfenac sodium 0.08%	$300/5ml	Postoperative ocular inflammation/pain	Diclofenac 0.1% drops – T1 (MAC) Flurbiprofen 0.03% drops – T1 (MAC) Ketorolac 0.5%, 0.4% drops – T1 (MAC)	Exclude, code 13
Micort-HC	Hydrocortisone acetate 2.5%	$253.03/28.4g	HIV Treatment	Generic hydrocortisone available T1 (MAC)	Exclude code 13; POS msg to use 2.5% cream
Vascepa	Icosapent ethyl 0.5g capsule	$1.37/cap	Hypertriglyceridemia	Vascepa 1g excluded. Gemfibrozil T1 (MAC)	Exclude, code 1

BRAND NAME	GENERIC NAME	PRICING (AWP)	INDICATION	SIMILAR THERAPIES ON FORMULARY	DUEC VOTE
Roxifol-D	Vitamin D3-Folic acid 500 unit tablet	$35.84/tab		Various Vit D preparations available T1 for <65 years old, $0 copay for 64 and older (MAC)	Exclude, code 13
Rayaldee	Calcifediol 30 mcg	$37.12/cap	Secondary hyperparathyroidism	Various Vit D preparations available T1 for <65 years old, $0 copay for 64 and older (MAC)	Exclude code 13
Dexeryl	Emollient Combination No. 104	$42/250g			Exclude, OTC. 250g on Ebay for $17.50
Pertzye	Lipase/protease/amylase 4000-14375	$1.78/cap	Pancreatic insufficiency	Other strengths of Pertzye excluded. Ultresa excluded. Zenpep, Creon, and Pancreaze available Tier 2	Exclude, code 13
Xultophy	Insulin degludec-liraglutide 100-3.6/ml		Type 2 diabetes	Various diabetes agents available at multiple tiers. Victoza T3 PA, Tresiba excluded (Rebated category)	Exclude, code 13
Basaglar	Insulin glargine, Hum recomb analog 100/ml	$75/pen	Diabetes	Rebated category. Lantus, Toujeo available Tier 2	Exclude, code13;

Dr. Kirtley motioned to exclude Yosprala. Dr. Pace seconded; all were in favor. Motion approved.
Dr. Kirtley motioned to exclude GoNitro. Dr. Golden seconded; all were in favor. Motion approved.
Dr. Simmons motioned to exclude Ameluz. Dr. Golden seconded; all were in favor. Motion approved.
Dr. Kirtley motioned to exclude Bromsite. Dr. Simmons seconded; all were in favor. Motion approved.
Dr. Kirtley motioned to exclude Micort-HC. Dr. Simmons seconded; all were in favor. Motion approved.
Dr. Kirtley motioned to exclude Vascepa. Dr. Pace seconded; all were in favor. Motion approved.
Dr. Pace motioned to exclude Roxifol-D. Dr. Simmons seconded; all were in favor. Motion approved.
Dr. Neill motioned to exclude Rayaldee. Dr. Simmons seconded; all were in favor. Motion approved.
Dr. Kirtley motioned to exclude Dexeryl. Dr. Simmons seconded; all were in favor.

Motion approved.
Dr. Kirtley motioned to exclude Pertzye. Dr. Neill seconded; all were in favor. Motion approved.
Dr. Neill motioned to excluded Xultophy. Dr. Pace seconded; all were in favor. Motion approved.
Dr. Neill motioned to exclude Basaglar. Dr. Pace seconded; all were in favor. Motion approved.

2. Specialty Medications

BRAND NAME	GENERIC NAME	PRICING (AWP)	INDICATION	SIMILAR THERAPIES ON FORMULARY	DUEC VOTE
Nudiclo	Diclofenac sodium-Capsaicin 1.5-0.025%	$4,768.39	Signs & symptoms of knee OA	Generic NSAIDs covered tier 1	Exclude, code 13, code 4 (kit policy)
Exondys 51	Eteplirsen	$960/ml	Duchenne muscular dystrophy		Exclude, code 1
Cuvitru	Immune Globulin G 1g/5ml, 2g/10ml, 4g/20ml, 8g/40ml	$40.32/mL	Multiple indications	Several covered T4PA pharmacy, no PA medical	Exclude, code 13
Orkambi	Lumacaftor-ivacaftor 100-125mg	$213.46/tablet	Cystic Fibrosis in kids 6-11 yrs	Orkambi for adults (200-125mg) covered Tier 4 PA	Exclude, code1. Exclude in patients 12 and younger due to no data on change in exacerbations and a nonsignificant improvement in FEV1.
Sustol	Granisetron 10mg/0.4ml	$594.0.4ml	Prevention of chemo associated N/V	Granisetron & ondansetron tabs T1 (QL0 (MAC) Emend, Varubi T2 (QL0 Sancuso T3 (QL)	Exclude, code 13
Aggrastat	Tirofiban HCl Monohydrate 2.75mg/15ml	$267.07	To support PCI for STEMI	NA Medical. Out of scope of pharmacy benefits.	Exclude from pharmacy benefit; Include on medical.

Dr. Golden motioned to Exclude Exondys 51. Dr. Neill seconded; all were in favor. Motion approved.

The committee recommended the proposed coverage for non-specialty additions, specialty additions, non-specialty exclusions, and specialty exclusions.

IV. Oral Antidiabetic Rebate Review: *by Dr. Rachael McCaleb, UAMS*

The purpose of this review was to evaluate the current literature regarding the efficacy and safety of non-insulin anti-diabetic agents (DPP-4 inhibitors, GLP-1 receptor agonists, and SGLT2 inhibitors) for glycemic control in adult patients with type 2 diabetics mellitus.

The committee recommended to <u>exclude</u> DPP4 Inhibitors, and allow for EBRx to rebate GLP-1 receptor agonists and SGLT2 inhibitors.

Mayfield requested additional cost information analysis comparing the DPP-4 to the SGL-2.

Pace recommended exclusion of the DPP-4 inhibitors. Simmons seconded; all were in favor.

Motion approved.

Dr. Kirtley motioned to begin the bid process to choose up to two each in the GLP1s and SGLT2s. Mayfield seconded; all were in favor.

Motion approved.

V. Opioid Discussion: *by Committee*

The committee will postpone the Opioid discussion until the next DUEC meeting in April.

VI. EBD Report*: by Dr. Geri Bemberg, UAMS*

Dr. Bemberg reported at the previous January 2017 Board meeting, Dr. Kirtley recommended to exclude the brand named Epi-Pen when the generic become available. The Board approved the recommendation. The new coverage will be as follows: Generic epinephrine Tier 2, Adrenaclick Tier 3, Epi-Pen brand excluded. Quantity limits will remain in place. Members will receive a 90-day notification.

Dr. Bemberg also reported Pharmacy had an increase in spending, but comparing 4th quarter 2016 to 4th quarter 2015 the plan spent approximately $1 million less. Comparing 2016 to 2015 total plan year, the plan experienced an increase of 3.84%, which is below the projected amount of 10% -12%.

Dr. Bemberg thanked the committee for all their hard work.

Meeting Adjourned.

Respectfully submitted,

Dr. Hank Simmons,
Chair, DUEC

***New Drug Code Key:**

1	Lacks meaningful clinical endpoint data; has shown efficacy for surrogate endpoints only.
2	Drug's best support is from single arm trial data
3	No information in recognized information sources (PubMed or Drug Facts & Comparisons or Lexicomp)
4	**Convenience Kit Policy** - As new drugs are released to the market through Medispan, those drugs described as "kits will not be considered for inclusion in the plan and will therefore be excluded products unless the product is available solely as a kit. Kits typically contain, in addition to a pre-packaged quantity of the featured drug(s), items that may be associated with the administration of the drug (rubber gloves, sponges, etc.) and/or additional convenience items (lotion, skin cleanser, etc.). In most cases, the cost of the "kit" is greater than the individual items purchased separately.
5	**Medical Food Policy** - Medical foods will be excluded from the plan unless two sources of peer-reviewed, published medical literature supports the use in reducing a medically necessary clinical endpoint. A medical food is defined below: A medical food, as defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), is "a food which is formulated to be consumed or administered eternally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." FDA considers the statutory definition of medical foods to narrowly constrain the types of products that fit within this category of food. Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or condition. Medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition, and all foods fed to sick patients are not medical foods. Instead, medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for a patient who is seriously ill or who requires use of the product as a major component of a disease or condition's specific dietary management.
6	**Cough & Cold Policy** - As new cough and cold products enter the market, they are often simply re-formulations or new combinations of existing products already in the marketplace. Many of these existing products are available in generic form and are relatively inexpensive. The new cough and cold products are branded products and are generally considerably more expensive than existing products. The policy of the ASE/PSE prescription drug program will be to default all new cough and cold products to "excluded" unless the DUEC determines the product offers a distinct advantage over existing products. If so determined, the product will be reviewed at the next regularly scheduled DUEC meeting.
7	**Multivitamin Policy** - As new vitamin products enter the market, they are often simply re-formulations or new combinations of vitamins/multivitamins in similar amounts already in the marketplace. Many of these existing products are available in generic form and are relatively inexpensive. The new vitamins are branded products and are generally considerably more expensive than existing products. The policy of the ASE/PSE prescription drug program will be to default all new vitamin/multivitamin products to "excluded" unless the DUEC determines the product offers a distinct advantage over existing products. If so determined, the product will be reviewed at the next regularly scheduled DUEC meeting.
8	Drug has limited medical benefit &/or lack of overall survival data or has overall survival data showing minimal benefit
9	Not medically necessary
10	Peer -reviewed, published cost effectiveness studies support the drug lacks value to the plan.
11	**Oral Contraceptives Policy** - OCs which are new to the market may be covered by the plan with a zero dollar, tier 1, 2, or 3 copay, or may be excluded. If a new-to-market OC provides an alternative product not similarly achieved by other OCs currently covered by the plan, the DUEC will consider it as a new drug. IF the drug does not offer a novel alternative or offers only the advantage of convenience, it may not be considered for inclusion in the plan.
12	Other
13	Insufficient clinical benefit OR alternative agent(s) available

Non-Insulin Anti-Diabetic Agents for Treatment of Type 2 Diabetes Mellitus

Rachael McCaleb, PharmD

February 2017

Executive Summary:

The purpose of this review was to evaluate the current literature regarding the efficacy and safety of non-insulin anti-diabetic agents (DPP-4 inhibitors, GLP-1 receptor agonists, and SGLT2 inhibitors) for glycemic control in adult patients with type 2 diabetes mellitus. The following conclusions are based on the information gathered from the literature:

- Based on non-comparative trials, it appears that the DPP-4 inhibitors improve glycemic parameters to a similar degree and have similar adverse event profiles.
  - Additionally DPP-4 inhibitors [saxagliptin, alogliptin, and sitagliptin] have a neutral effect on major adverse cardiovascular events (MACE) composite outcome of CV death, MI and ischemic stroke.
- As a class, all GLP-1 RAs have demonstrated significant reductions in HbA1c compared to placebo.
  - Head-to-head comparisons of GLP-1 RAs suggest that liraglutide may have the largest HbA1c lowering capability followed by exenatide OW and then exenatide BID.
  - Dulaglutide once weekly was more efficacious at lowering HbA1c compared with exenatide BID and was noninferior to liraglutide at lowering HbA1c.
  - In regards to cardiovascular outcomes, data is only available for exenatide, liraglutide, and lixisenatide.
    - Among patients with T2DM at increased risk for CVD, liraglutide was associated with a reduction in CV events when compared to placebo.
    - Among patients with T2DM at increased risk for CVD, lixisenatide was associated with a neutral effect on CV events when compared to placebo.
- As a class, SGLT2 inhibitors are effective in lowering HbA1c compared to placebo.
  - There are no head-to-head trials between any of the SGLT2 inhibitors. However, indirect comparisons suggest that canagliflozin 300 mg reduced HbA1c, FPG and systolic blood pressure to a greater extent compared with dapagliflozin and empagliflozin at any dose.
    - Direct SGLT2 inhibitor comparisons would further delineate their comparative efficacy and tolerability.
  - In regards to cardiovascular outcomes, evidence suggest that SGLT2 inhibitors protect against risk of MACE, CV death, and all-cause death. Empagliflozin is associated with a significantly lower risk compared to placebo.
- When compared to sitagliptin, GLP-1 RAs [exenatide OW, liraglutide, and dulaglutide] are more effective for glycemic control and weight loss with similar effects on reducing blood pressure and lipid parameters.

Recommendations:

- EBD Formulary may include zero up to two covered products <u>in each subcategory</u> all other products will be excluded.

Dipeptidyl-Peptidase 4 (DPP-4) Inhibitors

Introduction

Currently, there are four DPP-4 inhibitors available in the United States: alogliptin, linagliptin, saxagliptin, and sitagliptin. None of the DPP-4 inhibitors are available generically. All 4 agents are approved to be used as monotherapy and in combination with other anti-diabetic agents (metformin, sulfonylureas, thiazolidinediones, and insulin).

Efficacy

Systematic reviews and meta-analysis of DPP-4 inhibitors have demonstrated the effects across the class in terms of HbA_{1c} mean change from baseline, fasting plasma glucose from baseline, and proportion of patients portion of patients achieving HbA_{1c} <7% for monotherapy as well as add-on therapy, in patients with type 2 diabetes.

Monotherapy

Aroda VR, Henry RR, Han J, et al. Efficacy of GLP-1 receptor agonists and DPP-4 inhibitors: meta-analysis and systematic review. *Clin Ther* 2012;34:1247-58

- Studies included were randomized controlled trials (RCTs) of ≥12 weeks' duration in patients with type 2 diabetes studying the effects of adding a single drug (not multiple therapies).
    - A total of 44 trials with DPP-4 inhibitors were identified for analysis.
- Results:
    - For the highest maintenance dose studied, the mean changes in HbA_{1c} from baseline were alogliptin, -0.69 [-0.85 to -0.54]; linagliptin, -0.60 [-0.75 to -0.46]; saxagliptin, -0.68 [-0.78 to -0.57]; and sitagliptin, -0.67 [-0.75 to -0.60].
    - Additionally, fasting plasma glucose (FPG) was significantly reduced from baseline with all of the DPP-4 inhibitors. The mean changes in FPG with the DPP-4 inhibitors were −0.97, −1.04, −0.73, and −0.87 mmol/L (alogliptin, linagliptin, saxagliptin, and sitagliptin, respectively).
- Conclusion:
    - All of the DPP-4 inhibitors appeared to have been associated with similar mean decreases in HbA1c and FPG.

Park H, Park C, Kim Y, Rascati KL. Efficacy and safety of dipeptidyl peptidase-4 inhibitors in type 2 diabetes: meta-analysis. *Ann Pharmacother* 2012;46:1453-69.

- Meta-analysis included RCTs of DPP-4 inhibitors (sitagliptin, saxagliptin, vildagliptin, and linagliptin) in patients with type 2 diabetes.
    - A total of 14 trials with DPP-4 inhibitors (sitagliptin, saxagliptin, and linagliptin) compared to placebo were identified for analysis.
- Results:
    - DPP-4 inhibitors lowered HbA1c significantly more than placebo (WMD -0.88%; 95% CI -1.02 to -0.75, [I^2 = 85%])
        - WMD by agent
            - Sitagliptin (9 trials) -0.98; 95% CI -1.18 to -0.78
            - Saxagliptin (6 trials) -0.52; 95% CI -0.63 to -0.42
            - Linagliptin (4 trials) -0.74; 95% CI -1.01 to -0.47

  Heterogeneity was reduced with the exclusion of trials (n=7) investigating only Japanese patients (WMD -0.69%; 95% CI -0.77 to -0.62, [I^2 = 41%])

Head-to-head comparison

Only able to locate one direct comparison trial with the DPP-4 inhibitors. The efficacy of saxagliptin versus sitagliptin, each in combination with metformin, in patients with type 2 diabetes. The addition of saxagliptin or sitagliptin to metformin therapy produced similar decreases in mean HbA1c from baseline at 18 weeks (adjusted mean change -0.52% and -0.62%, respectively). Thus, saxagliptin added to metformin was noninferior to sitagliptin added to metformin.

Cardiovascular Outcomes:

The SAVOR-TIMI-53 and EXAMINE trials assessed CV safety of saxagliptin and alogliptin, respectively. These trials found that there was a neutral effect on major adverse cardiovascular events (MACE) composite outcome of CV death, MI and ischemic stroke. Both trials had were short in duration of follow-up, 2.1 years and 18 month, respectively. The TECOS trial aimed to assess the long-term effect on CV events of sitagliptin in T2DM patients with CVD. The median follow-up duration was 3 years. The results showed that sitagliptin was NI to placebo for adverse cardiovascular events (MACE) composite outcome of CV death, MI, ischemic stroke, and hospitalization for unstable angina. In conclusion, DPP-4 inhibitors do not seem to have any effect on major adverse cardiovascular outcomes and risk for heart failure, apart from saxagliptin which was associated with an increased risk for hospitalization for heart failure.

Summary

Based on non-comparative trials, it appears that the DPP-4 inhibitors improve glycemic parameters to a similar degree and have similar adverse event profiles; however, one cannot conclude with certainty if differences exist between agents given the scarcity of comparative trials. Additionally, evidence suggest no cardiovascular harm (or benefit) with DPP-4 inhibitors.

Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist

Introduction

Currently, there are five GLP-1 receptor agonists available in the United States: albiglutide, dulaglutide, exenatide liraglutide, and lixisenatide. The short-acting GLP-1RAs include exenatide twice daily, liraglutide once daily, and lixisenatide once daily. The approved long-acting GLP-1RAs are administered weekly and are exenatide, albiglutide, and dulaglutide. Exenatide is available as a short-acting formulation administered twice daily (Byetta®) and a long-acting formulation administered once weekly (Bydureon®). Liraglutide (Victoza®) is indicated for use in type 2 diabetes but is also available under the brand name Saxenda® which indicated for chronic weight management. None of the GLP-1 receptor agonists are available generically. All 5 agents are approved to be used as monotherapy and in combination with other anti-diabetic agents.

Efficacy

Eight head-to-head trials have evaluated the safety and efficacy of GLP-1 RA active comparators. Additionally, two unpublished head-to-head trials were located on ClinicalTrials.gov.

Study	Design	Background therapy	Active comparators
DURATION-1 Drucker et al. 2008	N=295, 30 weeks	Drug naïve or metformin, SU, TZD or a combination of two of those agents	Exenatide 10 µg BID Exenatide 2 mg QW
NCT01652716	N=375, 28 weeks	Drug naïve or metformin, SU, TZD or a combination of two of those agents	Exenatide 10 µg BID Exenatide 2 mg QW
LEAD-6 Buse et al. 2009	N=464, 26 weeks	Metformin, SU, or both	Exenatide 10 µg BID Liraglutide 1.8 mg QD
DURATION-5 Blevins et al. 2011	N=252, 24 weeks	Drug naïve or metformin, SU, TZD or any combination	Exenatide 10 µg BID Exenatide 2 mg QW

DURATION-6 Buse et al. 2013	N=911, 26 weeks	Metformin, SU, both, or metformin + pioglitazone	Exenatide 2 mg QW Liraglutide 1.8 mg QD
GetGoal-X Rosenstock et al. 2013	N=634, 24 weeks	Metformin	Lixisenatide 20 µg QD Exenatide 10 µg BID
NCT01973231	N=404, 26 weeks	Metformin	Liraglutide 1.8 mg QD Lixisenatide 20 µg QD
HARMONY-7 Pratley et al. 2014	N=841, 32 weeks	Metformin, pioglitazone, SU, or any combination	Albiglutide 50 mg QW Liraglutide 1.8 mg QD
AWARD-1[a] Wysham et al. 2014	N=978, 26 weeks	Metformin + pioglitazone	Dulaglutide 1.5 mg QW Dulaglutide 0.75 mg QW Exenatide 10 µg BID Placebo
AWARD-6 Dungan et al. 2014	N=599, 26 weeks	Metformin	Dulaglutide 1.5 mg QW Liraglutide 1.8 mg QD

[a] Superiority testing versus placebo, noninferiority testing versus exenatide

Study	**Mean change in HbA_{1c}**	**Proportion of patients able to reach HbA_{1c} <7%**	**Adverse events (AEs)**
DURATION-1 Drucker et al. 2008	*Exenatide BID*: -1.5% *Exenatide QW*: -1.9% p=0.0072	*Exenatide BID*: 61% *Exenatide QW*: 77% p=0.0039	*Exenatide BID*: higher incidence of n/v *Exenatide QW*: higher incidence of injection site reactions
NCT01652716	*Exenatide BID*: -1.02% *Exenatide QW*: -1.39% p=0.0023	*Exenatide BID*: 43% *Exenatide QW*: 49% p=0.2247	*Exenatide BID*: higher incidence of n/v *Exenatide QW*: higher incidence of injection site reactions
LEAD-6 Buse et al. 2009	*Exenatide BID*: -0.79% *Liraglutide QD*: -1.12% p<0.0001	*Exenatide BID*: 43% *Liraglutide QD*: 54% p=0.0015	Lower overall AEs with *liraglutide* but more severe AES with *liraglutide*
DURATION-5 Blevins et al. 2011	*Exenatide BID*: -0.9% *Exenatide QW*: -1.6% p<0.0001	*Exenatide BID*: 30% *Exenatide QW*: 58% p<0.0001	*Exenatide BID*: higher incidence of n/v *Exenatide QW*: higher incidence of injection site reactions
DURATION-6 Buse et al. 2013	*Exenatide QW:* -1.28% *Liraglutide QD*: -1.48%* p=0.02	*Exenatide QW*: 53% *Liraglutide QD*: 60% p=0.0011	*Exenatide QW*: higher incidence of injection site reactions *Liraglutide*: higher incidence of n/v
GetGoal-X Rosenstock et al. 2013	*Lixisenatide QD*: -0.79% *Exenatide BID*: -0.96%	*Lixisenatide QD*: 48.5% *Exenatide BID*: 49.8% p=NS	*Lixisenatide*: lower GI AEs and fewer episodes of symptomatic hypoglycemia
NCT01973231	*Liraglutide QD:* -1.81% *Lixisenatide QD:* -1.24& p=NR	*Liraglutide QD:* 74% *Lixisenatide QD:* 46% p=NR	*Liraglutide QD* more AEs compared to lixisenatide
HARMONY-7 Pratley et al. 2014	*Albiglutide QW*: -0.79% *Liraglutide QD*: -0.99% p=0.0846	_____	*Albiglutide QW*: higher incidence of injection site reactions *Liraglutide QD*: higher incidence of n/v
AWARD-1 Wysham et al. 2014	*Dulaglutide QW*: -1.51% *Dulaglutide QW*: -1.3% *Exenatide BID*: -0.99% Placebo-0.46% p<0.001[a]	*Dulaglutide QW*: 78% *Dulaglutide QW*: 66% *Exenatide BID*: 52% p<0.001	AEs were similar
AWARD-6 Dungan et al. 2014	*Dulaglutide QW*: -1.42% *Liraglutide QD*: -1.36% p<0.0001	*Dulaglutide QW*: 68% *Liraglutide QD*: 68%	AEs were similar

[a] Both doses of dulaglutide were superior to exenatide *liraglutide was superior to weekly exenatide for HbA1c lowering

Cardiovascular Outcomes

Exenatide

Best et al.

A retrospective database analysis (n=383,525) among patients with type 2 diabetes determined that exenatide-treated patients were less likely to have a CVD event than non-exenatide-treated patients (HR 0.81; 95% CI 0.68 – 0.95; p=0.01) and lower rates of CVD-related hospitalization (HR 0.88; 95% CI 079 – 0.98; p=0.02) and all-cause hospitalization (HR 0.94; 0.91 – 0.97; p<0.001).

- A greater proportion of exenatide users had indicators for CVD (HLD, HTN, arrhythmia, CHF, ACS) and used medications to treat CVD risk factors (antihypertensive agents and antihyperlipidemic agents) compared to non-exenatide users (p<0.001).

Ratner et al.

A pooled analysis of the CV safety data from 12 studies with exenatide BID was used to determine to CV safety of exenatide BID in patients with type 2 diabetes compared to placebo or insulin. The data included 1,072 patient-years (PY) exposure to exenatide and 780 PY exposure to comparators. The results showed that Primary Major Adverse CV Events (CV mortality, stroke, MI, ACS, and revascularization procedures) RR was 0.7 (95% CI 0.38 – 1.31) favoring exenatide. In conclusion, this study showed that there was not an increased in CV risk associated with use of exenatide BID vs comparator.

- There were low numbers of CV events in both groups (exenatide BID: 20/2316 and comparator: 18/1629).

Liraglutide

LEADER Trial

RCT among patients with type 2 diabetes and high cardiovascular risk (n=9340) were randomized to liraglutide daily or placebo. The rate of the first occurrence of death from CV causes, nonfatal MI, or nonfatal stroke was lower among patients in the liraglutide group (608/4668) compared to the placebo group (694/4672) (HR 0.87; 95% CI 0.78 – 0.97; p<0.001 for noninferiority; p=0.01 for superiority). Additionally, the liraglutide group had a lower rate of death from any cause compared to placebo (HR 0.85; 95% CI, 0.74 – 0.97; p=0.02).

Lixisenatide

ELIXA Trial

RCT in patients with T2DM and recent ACS (MI or hospitalization for unstable angina in prior 180 days). The results showed there was no difference in composite of time to death from cardiovascular causes, nonfatal MI, nonfatal stroke, or unstable angina requiring hospitalization in patients treated with lixisenatide versus placebo (6.4 events per 100 patient years v 6.3 events, respectively, p=0.81).

Summary

As a class all GLP-1 RAs have demonstrated significant reductions in HbA1c compared to placebo. Head-to-head comparisons of GLP-1 RAs suggest that liraglutide may have the largest HbA1c lowering capability followed by exenatide once weekly and then exenatide twice daily. Dulaglutide once weekly was more efficacious at lowering HbA1c compared with exenatide twice daily and was noninferior to liraglutide at lowering HbA1c. In regards to cardiovascular outcomes, a retrospective analysis and pooled analysis was located for exenatide and randomized controlled clinic trials were located for liraglutide and lixisenatide. .

Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitor

Introduction

The FDA has approved three SGLT2 inhibitors: canagliflozin, dapagliflozin, and empagliflozin. They are available as single-ingredient products and also in combination with metformin. Additionally, empagliflozin is available in combination with linaglitpin (Glyxambi®). As a class, SGLT2 inhibitors reduce reabsorption of filtered glucose by the kidneys which leads to reductions in plasma glucose levels. These agents do not effect insulin secretion, therefore they do not increase the risk of hypoglycemia.

Efficacy

Zaccardi et al.

Systematic review and network meta-analysis of randomized controlled trials (≥24 weeks) including canagliflozin, dapagliflozin or empagliflozin. A total of 38 trials were included.

- All SGLT2 inhibitors showed significant reductions in HbA1c and FPG versus placebo (0.6–0.9% decrease in HbA1c and 1.1–1.9 mmol/l decrease in FPG).
- When compared to placebo, all SGLT2 reduced body weight (1.6–2.5 kg), systolic (2.8–4.9 mmHg) and diastolic (1.5–2.0 mmHg) blood pressure.
- Canagliflozin 300 mg reduced HbA1c, FPG and systolic blood pressure to a greater extent compared with dapagliflozin and empagliflozin at any dose.

Mean difference (95% confidence interval) *Only included statistically significant differences*

	Cana 300 mg	**Cana 100 mg**	**Dapa 10 mg**	**Dapa 5 mg**	**Empa 25 mg**	**Empa 10 mg**
Cana 300 mg	--------	-------	-0.21 (-0.33 to -0.08)	-0.3 (-0.45 to -0.15)	-0.2 (-0.33 to -0.08)	-0.26 (-0.29 to -0.03)
Cana 100 mg	-0.10 (-0.2 to -0.0)	-------	-------	-0.20 (-0.35 to -0.05)	-------	-0.16 (-0.29 to -0.03)

- Direct SGLT2 inhibitor comparisons would further delineate their comparative efficacy and tolerability.

Cardiovascular Outcomes

Zinman (EMPA-REG)

In patients with a history of CV disease, there was moderate strength of evidence that empagliflozin decreased the primary composite CV endpoint of CV death, non-fatal myocardial infarction (MI), or non-fatal stroke versus placebo (10.5% vs. 12.1%), with a NNT of 63 over 3.1 years (HR 0.86 (95% CI 0.74 to 0.99); P<0.001 for noninferiority; P=0.04 for superiority).

- Empagliflozin reduced death related to CV causes compared to placebo (5.9% vs. 3.7% [HR 0.62 (95% CI 0.49 to 0.77)] P<0.001).

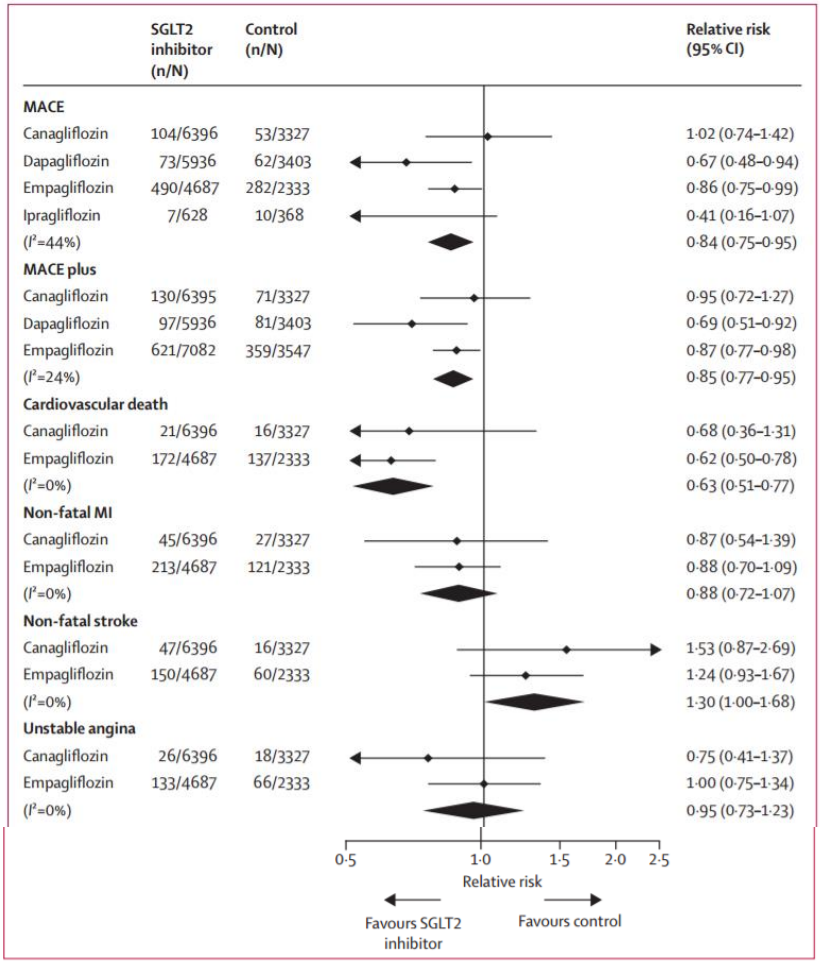
Tang et al.

A network meta-analysis of effects if SGLT2 inhibitor on CV outcomes and all-cause mortality. A total of 37 trials were identified.

- Only empagliflozin compared with placebo was significantly associated with lower risk of all-cause mortality (OR 0.67, 95% CI 0.56 to 0.81) and MACE (OR 0.81, 95% CI 0.70 to 0.93).
  - Significant effect was largely driven by the results of the EMPA-REG OUTCOME trial.
- Neither dapagliflozin nor canagliflozin was significantly associated with any harm.

Wu et al.

A systematic review and meta-analysis aimed to establish the effects of SGLT2 inhibitors on cardiovascular events, death, and safety outcomes in adults with type 2 diabetes, both overall and separately for individual drugs.



Authors concluded strong evidence that SGLT2 inhibitors protect against risk of MACE, MACE plus, CV death, and all-cause death. For every outcome, the effects were heavily affected by the findings for empagliflozin.

Summary

SGLT2 inhibitors are effective in lowering HbA1c compared to placebo. There are no head-to-head trials between any of the SGLT2 inhibitors. However, indirect comparisons suggest that canagliflozin 300 mg reduced HbA1c, FPG and systolic blood pressure to a greater extent compared with dapagliflozin and empagliflozin at any dose. In regards to cardiovascular outcomes, evidence suggest that SGLT2 inhibitors protect against risk of MACE, CV death, and all-cause death. Empagliflozin is associated with a significantly lower risk compared to placebo.

DPP-4 inhibitors versus GLP-1 receptor agonist

DURATION-2	N=491, 26 wks RCT, DB	Exenatide 2 mg OW Sitagliptin 100 mg daily Pioglitazone 45 mg daily	HbA1c change from baseline: Exenatide -1.5% Sitagliptin -0.9% Treatment difference: –0·6% (95% CI –0·9 to –0·4, p<0·0001) Significantly more patients achieved HbA1c targets of less than 7·0% and 6·5% or lower with exenatide

DURATION-4	N=820, 26 wks RCT, DB	Exenatide 2 mg OW Sitagliptin 100 mg daily	HbA1c change from baseline: Exenatide -1.5% Sitagliptin -1.2% Treatment difference: p<0·0001 Significantly more patients achieved HbA1c targets of less than 7·0% and 6·5% or lower with exenatide
LIRA-DPP-4	N=665, 26 wks RCT, PG, OL	Liraglutide 1.2 mg daily Liraglutide 1.8 mg daily Sitagliptin 100 mg daily	HbA1c change from baseline: Liraglutide 1.2 mg -1.24% Liraglutide 1.8 mg -1.5% Sitagliptin -0.9% Treatment difference: LIRA 1.8 v SITA –0·6% (95% CI –0·77 to –0·43, p<0·0001); LIRA 1.2 v SITA -0.34% (95% CI -0.51 to -0.16, p<0.0001) Significantly more patients achieved HbA1c targets of less than 7·0% and 6·5% or lower with liraglutide
AWARD-5-EXT	N=1098, 104 wks	Dulaglutide 0.75 mg QW Dulaglutide 1.5 mg QW Sitagliptin 100 mg daily Placebo	HbA1c change from baseline: Dulaglutide 0.75 mg -0.99% Dulaglutide 1.5 mg -0.71% Sitagliptin -0.32% Treatment difference: DULA 0.75 v SITA –0·39% (95% CI –0·56 to –0·22, p<0·001); DULA 1.5 v SITA -0.67% (95% CI -0.84 to -0.5, p<0.001) Significantly more patients achieved HbA1c targets of less than 7·0% with dulaglutide

Summary:

When compared to sitagliptin, GLP-1 RAs [exenatide OW, liraglutide, and dulaglutide] are more effective for glycemic control and weight loss with similar effects on reducing blood pressure and lipid parameters.

- However, they are associated with more GI AEs compared to sitagliptin. Additionally, they are only available as subcutaneous injections.

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Non-Insulin Anti-Diabetic Agents for Treatment of Type 2 Diabetes Mellitus

Rachael McCaleb, PharmD

February 2017

Generic Name	Brand Name	Manufacturer	Strengths	Generic
Dipeptidyl Peptidase-4 Inhibitor				
Alogliptin	Nesina®	Takeda	6.25 mg, 12.5 mg, 25 mg	Yes
Linagliptin	Tradjenta®	Boehringer Ingelheim	50 mg	No
Saxagliptin	Onglyza®	AstraZeneca	2.5 mg, 5 mg	No
Sitagliptin	Januvia®	Merck	25 mg, 50 mg, 100 mg	No
Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist				
Albiglutide (SubQ)	Tanzeum	GSK	30 mg, 50 mg	No
Dulaglutide (SubQ)	Trulicity	Eli Lilly	0.75 mg/0.5 mL, 1.5 mg/0.5 mL	No
Exenatide (SubQ)	Bydureon[a], Byetta[b]	AstraZeneca	Bydureon: 2 mg Byetta: 5 mcg/ 0.04 mL, 10 mcg/ 0.02 mL	No
Liraglutide (SubQ)	Saxenda[c], Victoza[d]	Novo Nordisk	18 mg/3 mL	No
Lixisenatide (SubQ)	Adlyxin	Sanofi-Aventis	10 mcg/0.2 mL and 20 mcg/0.2 mL	No
Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitor				
Canagliflozin	Invokana	Janssen	100 gm, 300 mg	No
Dapagliflozin	Farxiga	AstraZeneca	5 mg, 10 mg	No
Empagliflozin	Jardiance	Boehringer Ingelheim	10 mg, 25 mg	No

[a] Extended release formulation (once weekly); [b] Immediate release formulation (twice daily); [c] Saxenda labeled indication: chronic weight management; [d] Victoza labeled indication: type 2 diabetes mellitus

Combination Products		
Generic Name	**Brand Name**	**Manufacturer**
Alogliptin/metformin	Kazanoe®	Takeda
Alogliptin/pioglitazone	Oseni®	Takeda
Linagliptin/empagliflozin	Glyxambi®	Boehringer Ingelheim
Linagliptin/metformin	Jentadueto®, Jentadueto XR®	Boehringer Ingelheim
Saxagliptin/metformin	Komboglyze®	AstraZeneca
Sitagliptin/metformin	Janumet®, Janumet XR®	Merck
Sitagliptin/simvastatin	Juvisync™	Merck
Insulin degludec/liraglutide	Xultophy	Novo Nordisk
Insulin glargine/lixisenatide	Soliqua	Sanofi-Aventis
Canagliflozin/metformin	Invokamet, Invokamet XR	Janssen
Dapagliflozin/metformin	Xigduo XR	AstraZeneca
Empagliflozin/metformin	Synjardy	Boehringer Ingelheim

Arestin
Minocycline periodontal microspheres

Indication: Periodontitis

Dosing: Given subgingival; variable-dose product; dependent upon the size, shape, and number of pockets being treated. Professional administration is accomplished by inserting the unit-dose cartridge to the base of the periodontal pocket and then expelling the powder into the pocket.

Cost: 1mg (1 dose): $121.39

Evidence

From Package Insert[1]

2 multicenter, investigator-blind, vehicle-controlled, parallel-design studies (each with 3 arms) included a total of 748 patients (OPI-103A = 368; OPI-103B = 380) with generalized mod-adv adult periodontitis characterized by a mean probing depth of 5.90 and 5.81mm respectively were enrolled. Randomized to 1 of 3 groups: scaling and root planning, scaling and root planning +vehicle (bioresorbable polymer, PGLA), or scaling and root planning + Arestin. Pts were required to have 4 teeth w/ periodontal pockets of 6-9mm that bled on probing, but tx was administered to all sites with mean probing depths of 5mm or greater. Those with poor glycemic control or active infectious disease were excluded. Retreatment occurred at 3 and 6 months after initial tx, and any new site also received tx.

Probing Pocket Depth at Baseline and Change in Pocket Depth at 9 Months from 2 Multicenter US Clinical Trials

	Study OPI-103A N=368			**Study OPI-103B N=380**		
	SRP Alone N=124	**SRP + Vehicle N=123**	**SRP + Arestin N=121**	**SRP Alone N=126**	**SRP + Vehicle N=126**	**SRP + Arestin N=128**
PD (mm) at baseline	5.88±	5.91±	5.88±	5.79±	5.82±	5.81±
Mean ± SE	0.04	0.04	0.04	0.03	0.04	0.04
PD (mm) Change From Baseline	-1.04	-0.90	-1.20*$^{+}$	-1.32	-1.30	-1.63**$^{++}$
At 9 months Mean ± SE	±0.07	±0.54	±0.07	±0.07	±0.07	±0.07

SE = standard error; SRP = scaling and root planning; PD = pocket depth
Significantly different from SRP: *(P ≤0.05); **(P ≤0.001).
Significantly different from SRP + vehicle: $^{+}$(P ≤0.05); $^{++}$(P ≤0.001)

Mean Pocket Depth Change in Patient with Mean Baseline PD ≥5mm, ≥6mm, and ≥7mm at 9 Months from 2 Multicenter US Clinical Trials

	Study OPI-103A			**Study OPI-103B**		
Mean Baseline Pocket Depth	**SRP Alone**	**SRP + Vehicle**	**SRP + Arestin**	**SRP Alone**	**SRP + Vehicle**	**SRP + Arestin**
≥5mm (n)	-1.04mm	-0.90mm	-1.20mm*	-1.32mm	-1.30mm	-1.63mm*
	(124)	(123)	(121)	(126)	(126)	(128)
≥6mm (n)	-0.91mm	-0.77mm	-1.40mm*	-1.33mm	-1.46mm	-1.69mm*
	(34)	(46)	(45)	(37)	(40)	(25)
≥7mm (n)	-1.10mm	-0.46mm	-1.91mm	-1.72mm	-1.11mm	-2.84mm
	(4)	(5)	(3)	(3)	(3)	(2)

*Statistically significant comparison between SRP + Arestin and SRP alone.

From Journal of the American Dental Association[2]

For patients with moderate to severe chronic periodontitis, clinicians may consider locally delivered minocycline microspheres as an adjunct to SRP, but the net benefit is uncertain. – Strength of recommendation was rated as Expert Opinion For (Defined as: Evidence is lacking; the level of certainty is low. Expert opinion guides this recommendation.)

Level of Certainty: Low; 5 randomized controlled trials with 572 participants, moderately inconsistent results, but serious imprecision

Benefit: The best estimate for the treatment effect is a 0.24mm (95% CI -0.06 to 0.55) clinical attachment level gain. This is a *small* effect. Larger (*moderate*) effects, but also no (*zero*) effects, are also compatible with the data. Notable harmful effects from the treatment are improbable.

Adverse effects: Some potential adverse effects, but most are mild and transitory

Net benefit rating: Uncertainty in the balance between benefits and harms because benefits are unclear

Recommendation: Exclude on medical and pharmacy

References

1. Arestin Package Insert. www.valeant.com
2. Smiley CJ, Tracy SL, Abt E, et al. Evidence-Based Clinical Practice Guideline on the Nonsurgical Treatment of Chronic Periodontitis by Means of Scaling and Root Planing with or without Adjuncts. JADA 2015:146(7):525-535.

DUEC

Sept 5, 2016 - Nov 28, 2016 New Drug File

BRAND NAME	GENERIC NAME	PRICING (AWP)	INDICATION	SIMILAR THERAPIES ON FORMULARY/AWP	Jill's NOTES	DUEC VOTE	DUEC DATE	IB VOTE	IB DATE	
NON-SPECIALTY DRUGS										
Vaxchora	Cholera Vaccine	$270 (100mL)	Cholera prevention		Effective vaccine (90%); effectiveness wanes at 3 months (79%). Options: 1. Exclude (consider it an optional travel vaccine), 2. T3 (make it available to everyone at this copay), or 3. T3PA (copay and with planned travel to Africa, Southeast Asia, or Haiti, (or as the CDC advises).		2017 02 06		2017 02 21	
Yosprala	Aspirin-omeprazole 81-40mg, 325-40mg	$6/tablet	Secondary prevention of CV and cerebrovascular events	aspirin & omeprazole covered tier 1 (MAC)	Exclude, code 13		2017 02 06		2017 02 21	
GoNitro	Nitroglycerin powder pack 400mg	$8.17/pack	Treatment or prevention of angina pectoris	Nitroglycerin caps & sublingual tabs available tier 1 (MAC)	Exclude, code 13		2017 02 06		2017 02 21	
Ameluz	Aminolevulinic acid 10%	$324	Actinic keratoses		Exclude through pharmacy. Cover through medical.		2017 02 06		2017 02 21	
Bromsite	Bromfenac sodium 0.08%	$300/5mL	Postoperative ocular inflammation/pain	Diclofenac 0.1% drops - T1 (MAC) Flurbiprofen 0.03% drops - T1 (MAC) Ketorolac 0.5%, 0.4% drops - T1 (MAC)	T3		2017 02 06		2017 02 21	
Micort-HC	Hydrocortisone acetate 2.5%	$253.03/28.4g		Generic hydrocortisone available T1 (MAC)	Exclude, code 13; POS msg to use 2.5% cream in base		2017 02 06		2017 02 21	
Vascepa	Icosapent ethyl 0.5g capsule	$1.37/cap	Hypertriglyceridemia	Vascepa 1g excluded. Gemfibrozil T1 (MAC)	Exclude, code 1		2017 02 06		2017 02 21	
Roxifol-D	Vitamin D3-Folic acid 500unit tablet	$35.84/tab		Various Vit D preparations available T1 for <65 years old, $0 copay for 65 and older (MAC)	Exclude, code 13		2017 02 06		2017 02 21	
Rayaldee	Calcifediol 30mcg	$37.12/cap	Secondary hyperparathyroidism	Various Vit D preparations available T1 for <65 years old, $0 copay for 65 and older (MAC)	Exclude, code 13		2017 02 06		2017 02 21	
Dexeryl	Emollient Combination No. 104	$42/250g			Exclude, OTC. 250g on Ebay for $17.50, free shipping.		2017 02 06		2017 02 21	
Pertzye	Lipase/protease/amylase 4000-14375	$1.78/cap	Pancreatic insufficiency	Other strengths of Pertzye excluded. Ultresa excluded. Zenpep, Creon, and Pancreaze available Tier 2	Exclude, code 13.		2017 02 06		2017 02 21	
Xultophy	Insulin degludec-liraglutide 100-3.6/mL		Type 2 diabetes	Various diabetes agents available at multiple tiers. Victoza T3 PA, Tresiba excluded (Rebated category)	Exclude, code 13.		2017 02 06		2017 02 21	
Basaglar	Insulin glargine, Hum recomb analog 100/mL	$75/pen	Diabetes	Rebated category. Lantus, Toujeo available Tier 2	Exclude, code 13; lantus is the rebated drug.		2017 02 06		2017 02 21	
							2017 02 06		2017 02 21	
SPECIALTY DRUGS							2017 02 06		2017 02 21	
Nudiclo	Diclofenac sodium-Capsaicin 1.5-0.025%	$4,768.39	Signs & symptoms of knee OA	Generic NSAIDs covered tier 1	Exclude, code 13, code 4 (kit policy)		2017 02 06		2017 02 21	
Exondys 51	Eteplirsen	960/mL	Duchenne muscular dystrophy		Exclude, code 1		2017 02 06		2017 02 21	

Cuvitru	Immune Globulin G	1g/5mL, 2g/10mL, 4g/20mL, 8g/40mL	Multiple indications	Several covered T4PA pharmacy, no PA medical	Exclude, code 13		2017 02 06	2017 02 21
Stelara	Ustekinumab 130mg/26mL	$1,919.99/vial	Crohn disease, Plaque psoriasis, Psoriatic arthritis	Rebated category. Other Stelara strengths covered non-preferred Tier 4 PA	T4PA. Require step through Humira before access to Stelara.		2017 02 06	2017 02 21
Orkambi	Lumacaftor-ivacaftor 100-125mg	$213.46/tablet	Cystic Fibrosis in kids 6-11yrs	Orkambi for adults (200-125mg) covered Tier 4 PA	Exclude, code 1. Exclude in patients 12 and younger due to no data on change in exacerbations and a nonsignificant improvement in FEV1.		2017 02 06	2017 02 21
Sustol	Granisetron 10mg/0.4mL	$594/0.4mL	Prevention of chemo associated N/V	Granisetron & ondansetron tabs T1 (QL) (MAC) Emend, Varubi T2 (QL) Sancuso T3 (QL)	Exclude, code 13		2017 02 06	2017 02 21
Inflectra	Infliximab-dyyb 100mg	$1,135.54/vial	Multiple indications	Rebated category.	T4PA; use in place of infliximab. Will require step therapy with Humira or Enbrel first before access.		2017 02 06	2017 02 21
Lartruvo	Olaratumab 500mg/50mL	$2,832/vial	Soft tissue sarcoma	Most covered antineoplastic agents are available T4PA	T4PA; substantial OS in STS.		2017 02 06	2017 02 21
Aggrastat	Tirofiban HCl Monohydrate 2.75mg/15mL	$267.07	To support PCI for STEMI	NA Medical. Out of scope of pharmacy benefits	Exclude from pharmacy benefit; Include on medical.		2017 02 06	2017 02 21
Vemlidy	Tenofovir alafenamide fumarate 25mg	$39.91/tab	Chronic Hep B		T4PA, QL #30/30d		2017 02 06	2017 02 21